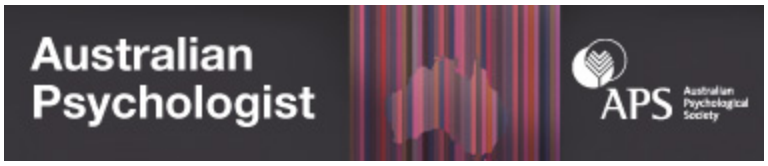
Readers and service commissioners require clear financial disclosures: Comment on innovation, research integrity, and change: A conflict of interest management framework for program developers (Sanders et al., 2019)



Readers and service commissioners require clear financial disclosures: comment on Innovation, research integrity, and change: A conflict of interest management framework for program developers (Sanders et al, 2019)

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Abstract:	Sanders et al's proposal for a management framework for conflicting interests among programme developers is very welcome. The underlying principles of such a framework must nevertheless prioritise the need for researchers and commissioners of services to make objective assessments of the impact of interventions reported in journal articles. This is particularly important in the field of randomised trials which may influence public sector expenditure. Using a strict definition derived from known financial conflict of interest, we have demonstrated that child-based effect sizes are much lower for independent studies than for studies with developer involvement. On this basis, we propose that journals publishing evaluations of psychosocial interventions should agree a standardised format for declarations of conflicts of interest based on that recommended by the International Committee of Medical Journal Editors.

We welcome this contribution by Sanders and colleagues (Matthew R. Sanders, Kirby, Toumbourou, Carey, & Havighurst) to the field of management of conflicting interests (CoI) by developers of psychosocial interventions. Their article usefully addresses the issues arising when researchers publish evaluations of programmes in which they have played a significant role as developers. Such issues are unavoidable, particularly in the early stages of programme development when developer involvement in research is, as the authors point out, often desirable. While Sanders et al write from the perspective of programme developers, we write this commentary from the perspective of evaluators and 'consumers' of published evaluations. Our focus is therefore on declarations of CoI in published papers and on their implications for data synthesis.

Declarations of CoI in psychosocial programmes

Eisner and colleagues (Eisner, Humphreys, Wilson, & Gardner, 2015) investigated the issue of declarations of conflicting interests by developers of parenting programmes published between 2008 and 2014, and found disappointingly low levels of disclosure. There is therefore no doubt that a CoI reporting framework for such programmes is timely.

Table 1, from Eisner et al's paper illustrates the magnitude of the problem at the time of publication.

TABLE 1 ABOUT HERE

CoI declarations were examined in published journal papers reporting on four internationally disseminated psychosocial interventions. A total of 136 articles were found which related to an intervention, were co-authored by intervention developers with a known financial conflicting interest, and were published in health sciences journals. CoI disclosures were coded for 134 articles. Overall, 92/134 (71%) of all articles were found to have absent, incomplete or partly misleading CoI disclosures. Disclosure rates for the four programs varied significantly between 11% (Triple P) and 73% (Multi-Systemic Therapy). Following guidelines published by the Committee for Publication Ethics, journal editors were contacted about 92 published articles with no CoI disclosure or a disclosure that was considered problematic. In 65/92 (71%) of all cases the editors published an 'erratum' or 'corrigendum'. In 16 of these cases the journal had mishandled a submitted disclosure. As Sanders and his colleagues point out, the most frequent reason for non-publication of an erratum was that the journal had no disclosure policy at the time of the publication (16 cases), and many of these journals have since instituted a CoI disclosure policy.

Sanders et al have highlighted the parallels with pharmaceutical industry trials, the interpretation of which has long been known to be vulnerable to commercial bias (Ahn et al., 2017). Cristea and Ioannidis (Cristea & Ioannidis, 2018) recently published a useful discussion paper addressing the CoI issues specific to trials of psychological interventions as opposed to pharmaceutical trials, in particular the difficulty in identifying an equivalent to a drug manufacturer. The authors point to the multiplicity of types of financial relationships between researchers and the psychosocial interventions under investigation and make a strong plea for a standardised approach to reporting. Cristea and Ioannidis' article also addresses the more nebulous concept of 'researcher allegiance' which can be even more difficult to capture.

Implications for data synthesis and meta-analyses

The lack of a generally accepted standardised definition of CoI leads to uncertainty in understanding the contribution of CoI to the impact of psychosocial interventions. In relation to drug trials, Ahn et al showed a strong independent association between the financial ties of principal investigators and positive clinical trial results. There is much less clarity in relation to psychosocial interventions.

In a systematic review and meta-analysis published in 2012, Wilson et al examined effect sizes for child behaviour outcomes reported in trials of the Triple P parenting programme, and concluded that characterisation of the contribution of the role of CoI was impossible at that time because 32 of the 33 eligible studies were authored by "Triple-P affiliated personnel" (Wilson et al., 2012). None of the trials had been registered with a trials registry and only two papers contained conflict of interest statements. The summary effect size in the meta-analysis of 23 trials was 0.61 (95%CI 0.42, 0.79) for maternally-reported child behaviour outcomes.

Subsequently Sanders and colleagues (M. R. Sanders, Kirby, Tellegen, & Day, 2014) tackled the issue of the contribution of CoI to Triple P effect sizes following the publication of a number of studies that they defined as independent of developer involvement. Developer involvement attributed through consensus of the authors was considered to be present "if the program developer was involved with study conceptualization, design, methodology, analyses, write up, or if the program developer was consulted in aspects of study design and implementation. If the program developer was involved in none of these aforementioned steps, the study was categorized as having no developer involvement." As well as papers published in peer-reviewed journals, the authors included data from a large number of unpublished studies. The summary effect size for child behavioural outcomes was reported as 0.525, and a modest but statistically significant moderator effect was seen for developer involvement. This effect became non-significant after adjusting for other moderator effects.

Using the same methodological approach described in our original 2012 meta-analysis, we have calculated effect sizes for studies published in peer-reviewed journals during the period covered by the Sanders et al meta-analysis. These are shown in table 2.

TABLE 2 ABOUT HERE

Thus widely different assessments of the association of CoI with study outcomes result from two differing definitions of developer involvement: using a strict definition derived from known financial CoI, Triple P child-based effect sizes cluster around zero for independent studies and greater than 0.5 for studies with developer involvement.

An additional issue that arises in Sanders et al's 2014 meta-analysis is that of the inclusion of unpublished studies. Bias may result if unpublished work by authors not well known to systematic reviewers is less likely to be included than unpublished work by others. Systematic reviews and meta-analyses may thus be more likely to include an unbiased selection of unpublished work if they are produced by completely independent authors or if they at least limit data synthesis to peer-reviewed published papers.

Conclusion and recommendations

Declarations of CoI in published evaluations of psychosocial interventions have been problematic until now and inconsistent reporting of CoI in published papers is a major problem that requires urgent attention. We consider that a standardised CoI declaration such as that recommended by the International Committee for Medical Journal Editors (ICMJE) should be required by psychology journal editors. The ICMJE CoI declaration (http://www.icmje.org/conflicts-of-interest/) focuses on direct and indirect financial interests, but other important factors including intellectual property rights and "other relationships or activities that readers could perceive to have influenced, or that give the appearance of potentially influencing" the content of a publication must also be declared. Sanders and his colleagues have helpfully suggested other specific areas which might be included in such a standardised declaration, including developer involvement in trial design, intervention allegiance and reputational factors.

Ahn, R., Woodbridge, A., Abraham, A., Saba, S., Korenstein, D., Madden, E., . . . Keyhani, S. (2017). Financial ties of principal investigators and randomized controlled trial outcomes: cross sectional study. *BMJ, 356*. doi:10.1136/bmj.i6770

Cristea, I.-A., & Ioannidis, J. P. A. (2018). Improving Disclosure of Financial Conflicts of Interest for Research on Psychosocial Interventions. *JAMA Psychiatry, 75*(6), 541-542. doi:10.1001/jamapsychiatry.2018.0382

Eisner, M., Humphreys, D., Wilson, P., & Gardner, F. (2015). Disclosure of financial conflicts of interests in interventions to improve child psychosocial health: A cross-sectional study. *PLoS ONE, 10*(11), e0142803. doi:10.1371/journal.pone.0142803

Sanders, M. R., Kirby, J. N., Tellegen, C. L., & Day, J. J. (2014). The Triple P-Positive Parenting Program: a systematic review and meta-analysis of a multi-level system of parenting support. *Clin Psychol Rev, 34*(4), 337-357. doi:10.1016/j.cpr.2014.04.003

Sanders, M. R., Kirby, J. N., Toumbourou, J. W., Carey, T. A., & Havighurst, S. S. Innovation, research integrity, and change: A conflict of interest management framework for program developers. *Australian Psychologist, 0*(0). doi:10.1111/ap.12404

Wilson, P., Rush, R., Hussey, S., Puckering, C., Sim, F., Allely, C., . . . Gillberg, C. (2012). How evidence-based is an 'evidence-based parenting program'? A PRISMA systematic review and meta-analysis of Triple P. *BMC Medicine, 10*(1), 130.

Table 1. Publications in peer-reviewed journals with and without CoI disclosures, four internationally disseminated psychosocial interventions,
Jan 2008–July 2014 (from Eisner et al 2015)

Row[1]	Characteristic	Triple P	NFP	MST	IY	Total
B	Included in analysis	79	14	25	16	134
C	COI fully disclosed, editor not contacted	8	8	16	10	42
D	Editor contacted	71	6	9	6	92
D1	CoI disclosure missing	60	4	9	6	79
D2	"No conflict of interest" statement	4	1	0	0	5
D3	Ambiguous or incomplete disclosure	7	1	0	0	8
E	No erratum/corrigendum published	13	5	6	2	26
E1	No disclosure policy	11	3	1	1	16
E2	Not program paper–journal/author response	0	0	3	0	3
E3	CoI deemed sufficient	1	0	0	0	1
E4	Unable/unwilling to examine	1	2	1	1	5
E5	No final response	1	0	1	0	2
F	Erratum/corrigendum announced	57	1	3	4	65
F1	Journal mishandling	14	0	2	0	16
F2	Authors submit corrected or new CoI	43	1	1	4	49
	Rates					
	Disclosure rate[2]	11%	57%	73%	63%	33%
	Errata rate[3]	80%	17%	33%	67%	71%

Notes
[1] See Eisner et al (2015) for coding scheme and operational definitions.
[2] Calculated as (C+E3)/(B-E2).
[3] Calculated as F/D.

Paper	Author(s) with financial interest	Standardised Mean Difference.
Schappin et al., 2013	No	-0.229
Little et al., 2013	No	-0.048
Malti, Ribeaud, & Eisner, 2011	No	0
Spijkers, Jansen, & Reijneveld, 2013	No	0.117
Gallart & Matthey, 2005	No	0.755
Median for papers without declared financial conflicting interests		**0.000**
Connell, Sanders, & Markie-Dadds, 1997	Yes	2.499
Nicholson & MR, 1999	Yes	0.342
Sanders, Markie-Dadds, Tully, & Bor, 2000	Yes	0.810
Sanders, Montgomery, & Brechman-Toussaint, 2000	Yes	0.321
Hoath & Sanders, 2002	Yes	0.610
Leung, Sanders, Leung, Mak, & Lau, 2003	Yes	1.000
Martin & Sanders, 2003	Yes	1.038
C. Markie-Dadds & M. R. Sanders, 2006	Yes	1.301
C. Markie-Dadds & M. Sanders, 2006	Yes	1.153
Morawska & Sanders, 2006	Yes	0.587
Turner & Sanders, 2006	Yes	-0.085
Roberts, Mazzucchelli, Studman, & Sanders, 2006	Yes	0.676
Yuki Matsumoto, Sofronoff, & Sanders, 2007	Yes	0.476
Turner, Richards, & Sanders, 2007	Yes	0.201
Plant & Sanders, 2007	Yes	0.254
Stallman & Ralph, 2007	Yes	0.412
Bodenmann, Cina, Ledermann, & Sanders, 2008	Yes	0.460
Hahlweg, Heinrichs, Kuschel, & Feldmann, 2008	Yes	0.782
Morawska & Sanders, 2009	Yes	0.306
Whittingham, Sofronoff, Sheffield, & Sanders, 2009	Yes	0.979
Wiggins, Sofronoff, & Sanders, 2009	Yes	0.567
Hahlweg, Heinrichs, Kuschel, Bertram, & Naumann, 2010	Yes	-0.161
Joachim, Sanders, & Turner, 2010	Yes	0.753
Y. Matsumoto, Sofronoff, & Sanders, 2010	Yes	0.109
Sanders, Stallman, & McHale, 2011	Yes	0.266

Cina et al., 2011	Yes	0.260
Morawska, Haslam, Milne, & Sanders, 2011	Yes	1.154
Sofronoff, Jahnel, & Sanders, 2011	Yes	0.156
Sanders, Baker, & Turner, 2012	Yes	0.890
Adamson, Morawska, & Sanders, 2013	Yes	0.600
Doherty, Calam, & Sanders, 2013	Yes	0.540
Haslam, Sanders, & Sofronoff, 2013	Yes	0.414
Leung, Fan, & Sanders, 2013	Yes	0.287
Roux, Sofronoff, & Sanders, 2013	Yes	1.040
Median for papers with financial conflicting interests		**0.553**

Table 2. Post-intervention standardised mean differences (SMD) for child behaviour outcomes between intervention and control groups in all Triple P trials reporting such outcomes published in peer reviewed journals before 2014. ECBI subscale data reported by Bodenmann et al were assumed to have been transposed, and are corrected here (see Wilson et al. (2012) for effect size calculation method).

Adamson, M., Morawska, A., & Sanders, M. R. (2013). Childhood feeding difficulties: a randomized controlled trial of a group-based parenting intervention. *Journal of Developmental & Behavioral Pediatrics, 34*(5), 293-302.

Bodenmann, G., Cina, A., Ledermann, T., & Sanders, M. R. (2008). The efficacy of the Triple P-Positive Parenting Program in improving parenting and child behavior: a comparison with two other treatment conditions. *Behaviour Research & Therapy, 46*(4), 411-427.

Cina, A., Röösli, M., Schmid, H., Lattmann, U. P., Fäh, B., Schönenberger, M., . . . Bodenmann, G. (2011). Enhancing positive development of children: Effects of a multilevel randomized controlled intervention on parenting and child problem behavior. *Family Science, 2*(1), 43-57. doi:10.1080/19424620.2011.601903

Connell, S., Sanders, M. R., & Markie-Dadds, C. (1997). Self-directed behavioral family intervention for parents of oppositional children in rural and remote areas. *Behavior Modification, 21*(4), 379-408.

Doherty, F. M., Calam, R., & Sanders, M. R. (2013). Positive parenting program (triple P) for families of adolescents with type 1 diabetes: a randomized controlled trial of self-directed teen triple P. *Journal of Pediatric Psychology, 38*(8), 846-858.

Gallart, S. C., & Matthey, S. (2005). The Effectiveness of Group Triple P and the Impact of the Four Telephone Contacts. *Behaviour Change, 22*(2), 71-80.

Hahlweg, K., Heinrichs, N., Kuschel, A., Bertram, H., & Naumann, S. (2010). Long-term outcome of a randomized controlled universal prevention trial through a positive parenting program: Is it worth the effort? *Child and Adolescent Psychiatry and Mental Health, 4*(14).

Hahlweg, K., Heinrichs, N., Kuschel, A., & Feldmann, M. (2008). Therapist-assisted, self-administered bibliotherapy to enhance parental competence: short- and long-term effects. *Behavior Modification, 32*(5), 659-681.

Haslam, D., Sanders, M., & Sofronoff, K. (2013). Reducing Work and Family Conflict in Teachers: A Randomised Controlled Trial of Workplace Triple P. *School Mental Health, 5*(2), 70-82. doi:10.1007/s12310-012-9091-z

Hoath, F. E., & Sanders, M. R. (2002). A feasibility study of Enhanced Group Triple P - Positive parenting program for parents of children with attention-deficit/hyperactivity disorder. *Behaviour Change.19 (4) (pp 191-206), 2002.Date of Publication: 2002.*(4), 2002.

Joachim, S., Sanders, M. R., & Turner, K. M. T. (2010). Reducing preschoolers' disruptive behaviour in public with a brief parent discussion group. *Child Psychiatry and Human Development, 41*(1), 47-60.

Leung, C., Fan, A., & Sanders, M. R. (2013). The effectiveness of a Group Triple P with Chinese parents who have a child with developmental disabilities: A randomized controlled trial. *Research in Developmental Disabilities, 34*(3), 976-984.

Leung, C., Sanders, M. R., Leung, S., Mak, R., & Lau, J. (2003). An outcome evaluation of the implementation of the Triple P-Positive Parenting Program in Hong Kong. *Family Process, 42*(4), 531-544.

Little, M., Berry, V., Morpeth, L., Blower, S., Axford, N., Taylor, R., . . . Tobin, K. (2013). The Impact of Three Evidence-Based Programmes Delivered in Public Systems in Birmingham, UK. *International Journal of Conflict and Violence, 6*(2), 260-272.

Malti, T., Ribeaud, D., & Eisner, M. (2011). The effectiveness of two universal preventive interventions in reducing children's externalizing behavior: A cluster randomized controlled trial. *Journal of Clinical Child & Adolescent Psychology, 40*(5), 677-692.

Markie-Dadds, C., & Sanders, M. (2006). A Controlled Evaluation of an Enhanced Self-Directed Behavioural Family Intervention for Parents of Children With Conduct Problems in Rural and Remote Areas. *Behaviour Change, 23*(1), 55-72.

Markie-Dadds, C., & Sanders, M. R. (2006). Self-directed Triple P (Positive Parenting Program) for mothers with children at-risk of developing conduct problems. *Behavioural and Cognitive Psychotherapy.34 (3) (pp 259-275), 2006.Date of Publication: Jul 2006.*(3), Jul.

Martin, A. J., & Sanders, M. R. (2003). Balancing work and family: A controlled evaluation of the Triple P-Positive Parenting Program as a work-site intervention. *Child and Adolescent Mental Health, 8*(4), 161-169.

Matsumoto, Y., Sofronoff, K., & Sanders, M. (2007). The efficacy and acceptability of the Triple P-Positive Parenting Program with Japanese parents. *Behaviour Change, 24*(4), 205-218.

Matsumoto, Y., Sofronoff, K., & Sanders, M. R. (2010). Investigation of the Effectiveness and Social Validity of the Triple P Positive Parenting Program in Japanese Society. *Journal of Family Psychology., 24*(1), 87-91.

Morawska, A., Haslam, D., Milne, D., & Sanders, M. R. (2011). Evaluation of a brief parenting discussion group for parents of young children. *Journal of Developmental and Behavioral Pediatrics., 2*(2), 136-145.
Morawska, A., & Sanders, M. (2009). An evaluation of a behavioural parenting intervention for parents of gifted children. *Behaviour Research and Therapy, 47*(6), 463-470.
Morawska, A., & Sanders, M. R. (2006). Self-administered behavioral family intervention for parents of toddlers: Part I. Efficacy. *Journal of Consulting & Clinical Psychology, 74*(1), 10-19.
Nicholson, J. M., & MR, S. (1999). Randomized controlled trial of behavioral family intervention for the treatment of child behavior problems in stepfamilies. *Journal of Divorce & Remarriage, 30*(3-4), 1-23.
Plant, K. M., & Sanders, M. R. (2007). Reducing problem behavior during care-giving in families of preschool-aged children with developmental disabilities. *Research in Developmental Disabilities, 28*(4), 362-385.
Roberts, C., Mazzucchelli, T., Studman, L., & Sanders, M. R. (2006). Behavioral family intervention for children with developmental disabilities and behavioral problems. *Journal of Clinical Child & Adolescent Psychology, 35*(2), 180-193.
Roux, G., Sofronoff, K., & Sanders, M. (2013). A randomized controlled trial of group stepping stones triple P: A mixed-disability trial. *Family Process, 52*(3), 411-424.
Sanders, M. R., Baker, S., & Turner, K. M. T. (2012). A randomized controlled trial evaluating the efficacy of Triple P Online with parents of children with early-onset conduct problems. *Behaviour Research and Therapy, 50*(11), 675-684.
Sanders, M. R., Markie-Dadds, C., Tully, L. A., & Bor, W. (2000). The triple P-positive parenting program: a comparison of enhanced, standard, and self-directed behavioral family intervention for parents of children with early onset conduct problems. *Journal of Consulting & Clinical Psychology, 68*(4), 624-640.
Sanders, M. R., Montgomery, D. T., & Brechman-Toussaint, M. L. (2000). The mass media and the prevention of child behavior problems: The evaluation of a television series to promote positive outcomes for parents and their children. *Journal of Child Psychology and Psychiatry and Allied Disciplines.41 (7) (pp 939-948), 2000.Date of Publication: 2000.*(7), 2000.
Sanders, M. R., Stallman, H. M., & McHale, M. (2011). Workplace Triple P: A Controlled Evaluation of a Parenting Intervention for Working Parents. *Journal of Family Psychology, 25*(4), 581-590.
Schappin, R., Wijnroks, L., Uniken Venema, M., Wijnberg-Williams, B., Veenstra, R., Koopman-Esseboom, C., . . . Jongmans, M. (2013). Brief parenting intervention for parents of NICU graduates: A randomized, clinical trial of Primary Care Triple P. *BMC Pediatrics, 13*(1).
Sofronoff, K., Jahnel, D., & Sanders, M. (2011). Stepping Stones Triple P seminars for parents of a child with a disability: A randomized controlled trial. *Research in Developmental Disabilities, 32*(6), 2253-2262.
Spijkers, W., Jansen, D., & Reijneveld, S. (2013). Effectiveness of Primary Care Triple P on child psychosocial problems in preventive child healthcare: a randomized controlled trial. *BMC Medicine, 11*(1), 240.
Stallman, H. M., & Ralph, A. (2007). Reducing risk factors for adolescent behavioural and emotional problems: A pilot randomised controlled trial of a self-administered parenting intervention. *Australian e-Journal for the Advancement of Mental Health, 6*(2), 1-13.
Turner, K. M., Richards, M., & Sanders, M. R. (2007). Randomised clinical trial of a group parent education programme for Australian indigenous families. *Journal of Paediatrics & Child Health, 43*(6), 429-437.
Turner, K. M., & Sanders, M. R. (2006). Help when it's needed first: a controlled evaluation of brief, preventive behavioral family intervention in a primary care setting. *Behavior Therapy, 37*(2), 131-142.
Whittingham, K., Sofronoff, K., Sheffield, J., & Sanders, M. R. (2009). Stepping Stones Triple P: an RCT of a parenting program with parents of a child diagnosed with an autism spectrum disorder. *Journal of Abnormal Child Psychology, 37*(4), 469-480.
Wiggins, T. L., Sofronoff, K., & Sanders, M. R. (2009). Pathways triple P-positive parenting program: Effects on parent-child relationships and child behavior problems. *Family Process., 48*(4), 517-530.
Wilson, P., Rush, R., Hussey, S., Puckering, C., Sim, F., Allely, C., . . . Gillberg, C. (2012). How evidence-based is an 'evidence-based parenting program'? A PRISMA systematic review and meta-analysis of Triple P. *BMC Medicine, 10*(1), 130.